

Remarks/Arguments

Personal Interview

The undersigned attorney wishes to thank the Examiner for the courtesy extended in the personal interview on July 31, 2003.

In the interview, the rejected claims were discussed, as were the cited U.S. patents to Morrow (No. 5,674,537) and Beattie et al. (5,364,344). Applicant's representative explained the differences between the disclosures of the cited art and Applicant's invention. In response, the Examiner made the helpful suggestion to amend the claims to recite that the source of peroxide and source of hypochlorite were from separate sources, and further that singlet oxygen was produced at the target site or during administration. The Examiner also requested that Applicant explain why Morrow's alleged production of hypochlorite and peroxide would not result in a sustained presence of singlet oxygen. The Examiner suggested that such amendments and remarks would distinguish the cited art.

This paper amends the claims as suggested by the Examiner and provides the requested explanation.

Information Disclosure Statement

In the Office Action, the Office indicates the Information Disclosure Statement filed April 19, 2002 failed to comply with the requirements of 37 C.F.R. § 1.98(a)(2), which requires submission of a legible copy of each U.S. and foreign patent, each publication or that portion which caused it to be listed, and all other information or that portion which caused it to be listed.

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In response, Applicants respectfully submit that the IDS filed April 19, 2002, was in conformance with the relevant rules. A date-stamped mailroom receipt, a copy of which is attached, indicates the Office received the IDS along with copies of the 131 documents attached. However, as it appears that the Patent Office misplaced the attached documents prior to forwarding the IDS to the Examiner, and out of courtesy to the Examiner, Applicants submit herewith another copy of that IDS, including the Form PTO-1449 and listed documents.

Claim Rejections - 35 U.S.C. § 102/103

The Office rejects claim 13 under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Morrow (U.S. Patent No. 5,674,537). The Office asserts that Morrow expressly discloses singlet oxygen falling within the scope of Applicant's claims, or alternatively, that Morrow discloses products that contain the exact same ingredients/components as that of the claimed invention.

In response, Applicant respectfully disagrees. Applicant's invention is directed to methods for the production of singlet oxygen and the use of those methods in therapeutic applications. Applicant has discovered that when a source of peroxide and a separate source of hypochlorite are combined, so that the combination occurs in the first instance in the locale of the target, that singlet oxygen is produced in a reaction that has myriad therapeutic effects. The production of singlet oxygen at the target site is an important, and recited, element of the claimed invention.

Morrow, on the other hand, describes electrolyzing a saline solution system to produce concentrated amounts of ozone and chlorine species for microbiocidal purposes, including intravenous injections in humans. Morrow's primary goal appears

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to be to create a single solution comprising both activated oxygen and chlorine species. Morrow states that possible saline electrolysis products include "chlorine, ozone, hydroxide, hypochlorous acid, hypochlorite, peroxide, oxygen . . . molecular hydrogen and sodium and hydrogen ions." (Paragraph spanning columns 4-5.) Morrow does not suggest that his solution will contain singlet oxygen.

Morrow discusses singlet oxygen formation only in the context of an *in vivo* "respiratory burst" or in other activities naturally occurring in warm-blooded animals. Morrow refers to singlet oxygen at column 1, line 65; column 2, lines 12, 37, 56, 60, and 66, and column 3, line 22, for example. Each of these references, however, relates to natural occurrences in a living animal, and each of these references occur within the patent before Morrow ever begins to discuss his own invention. Contrary to the Office's assertion, column 4, lines 65-68, and column 5, lines 1-3, do not mention singlet oxygen.

Those latter sections do, however, recite the presence of hypochlorite and peroxide in a single solution. That is, both peroxide and hypochlorite are recited as being products in Morrow's electrolyzed saline. The present invention teaches that, if kept separate until immediately prior to administration or until combined at the target site of administration, these compounds can be combined to yield singlet oxygen. However, their mere presence does not imply the sustained presence of singlet oxygen. As Applicant has repeatedly pointed out in his specification, singlet oxygen is a very short-lived species of oxygen, perhaps present for only 50 nanoseconds. (Page 24, paragraph 84.)

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Thus, if the peroxide and hypochlorite produced in Morrow's solution reacted to form singlet oxygen, that singlet oxygen would exist for only seconds, at most, after its formation. Additionally, water molecules in the suspending saline solution would rapidly quench any singlet oxygen that was present. As any possible singlet oxygen has almost certainly disappeared from his solution only seconds after electrolysis, it is appropriate that Morrow does not discuss its presence. Such a short life prevents the singlet oxygen, if it existed at all, from being administered in the methods of Morrow.

As noted above, peroxide and hypochlorite, *if kept separate*, can be combined at a target site so that singlet oxygen is produced in the vicinity of the target. This is exactly what is achieved in the present invention. Peroxide and hypochlorite, from separate sources, are combined only at the target site or during administration, thereby producing singlet oxygen in the vicinity of the target.

Applicant respectfully submits that the presently claimed invention is not disclosed by Morrow, either explicitly or inherently. Applicant respectfully requests the withdrawal of the rejection for anticipation and obviousness in view of Morrow.

Claim Rejections - 35 U.S.C. § 103

The Office rejects claims 1-4, 6-10, 12-16, and 29 as being unpatentable over Morrow (U.S. Patent No. 5,674,537) in view of Beattie *et al.* (U.S. Patent No. 5,364,344). The Office asserts that Morrow teaches the use of sodium hypochlorite, hydrogen peroxide, and singlet oxygen for treatment of tumors, which can be injected, and that moderating or neutralizing amounts of antioxidants or reducing agents may be coadministered (citing column 1, lines 35-68, columns 2-9, and column 10, lines 1-38).

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The Office cites Beattie *et al.* for the use of dual lumen catheters for delivering different fluids into the blood stream (citing the entire document).

In response, Applicant respectfully disagrees. Initially, Applicant submits that Morrow does not stand for the teachings the Office attributes to it. For example, Morrow does not teach the use of sodium hypochlorite, hydrogen peroxide, and singlet oxygen for treating tumors. As discussed extensively above, Morrow teaches the use of electrolyzed saline for its antimicrobial effect.

Morrow's electrolyzed saline is said to include peroxide and hypochlorite, but there is no mention of it containing singlet oxygen. In fact, as explained above, singlet oxygen would not be present at the time of administration. And while peroxide and hypochlorite, if kept separately, can be combined to produce singlet oxygen, Morrow has taken no such steps to prevent the reaction from occurring prematurely. Thus, there is no reason to believe that singlet oxygen would inherently be present in Morrow's solution, or would result from the peroxide/hypochlorite reaction after administration.

Finally, Applicant respectfully submits that Morrow does not mention tumors, cancer, or neoplasm of any kind. Morrow's discussion relates to treatment of foreign microbes, from bacteria to viruses, but not to treatment of tumors. Thus, Applicant also respectfully disagrees with this characterization of Morrow.

The Office cites Beattie *et al.* for the use of dual lumen catheters for delivering different fluids into the bloodstream. Without agreeing with this characterization of Beattie *et al.*'s teachings, Applicant respectfully submits that Beattie *et al.* does not remedy Morrow's deficiencies. At best, Beattie *et al.* offers a means for delivering

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separate reactants to the bloodstream, *if one desired to do that*. However, Beattie *et al.* provides no motivation to choose separate reactants, and certainly does not suggest what separate reactants could or should be.

And Morrow does not suggest separate reactants either. Morrow uses a single electrolyzed saline solution, which comprises a number of different components, allegedly including peroxide and hypochlorite. However, Morrow never suggests that these components could or should be separated for separate delivery. At best, Morrow suggests that his electrolyzed saline should be coadministered with other agents ("modulating agents"), such as ascorbic acid, for reducing the possibility of irreparable tissue damage from the electrolyzed saline (see paragraph spanning columns 9-10), or with other active agents such as colchicine (see column 10, line 38 *et seq.*).

The colchicine is preferably administered just prior to or concurrently with the electrolyzed saline (see column 13, lines 30-35), and the ascorbic acid is preferably administered about two to twenty minutes after the electrolyzed saline (see column 13, lines 40-47). Thus, if read in a light most favorable to the combination with Beattie *et al.*, one might deliver the electrolyzed saline through one lumen of the catheter, and a solution of colchicine through another, and another lumen of the multi-lumened catheter might be used to later deliver a solution of ascorbic acid. However, even in this light most favorable to the combination, the present invention does not result.

Applicant respectfully submits that the Office has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the Office must satisfy three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary

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skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (See M.P.E.P. § 2142.) In this instance, the Office has failed to satisfy all three criteria.

First, there is simply no motivation to modify the teachings of the cited art to arrive at the claimed invention. There is nothing in Morrow or Beattie et al. that would suggest the administration of a source of peroxide and a source of hypochlorite, *from separate sources*, to produce singlet oxygen *at the target site*. And there is certainly no expectation of success in the combination, as no steps have been taken to prevent the peroxide/hypochlorite reaction from taking place prior to reaching the target site. Finally, even in the combination, the cited art fails to teach or suggest each of Applicant's claimed method elements, including administration of a source of peroxide and a source of hypochlorite, *from separate sources*, to produce singlet oxygen *at the target site or during administration*.

In view of the foregoing, Applicant respectfully submits that the presently claimed invention is not obvious in view of the art of record, and respectfully requests the Office withdraw the rejections of record.

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Conclusion

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: August 25, 2003

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PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

In Re Application of: Randolph M. HOWES

Serial No.: 10/050,121

Group Art Unit: 1614

Filed: January 18, 2002

Examiner: not yet assigned

For: COMPOSITIONS, METHODS, APPARATUSES, AND SYSTEMS FOR SINGLET
OXYGEN DELIVERY

1. Information Disclosure Statement Under 37 C.F.R. §1.97(b)
2. PTO-1449 (6 pages)
3. 131 references

Dated April 19, 2002

Docket No.: 02514.0051-01

SMP/D.Long - Mail Drop 884



(Due Date: N/A)

DK 10
4-22-02